REMARKS

Due to the restriction required by the Office, which now has been made final, claims 8, 10-11, 15-30 and 32 have been withdrawn by the examiner as directed to non-elected subject matter. Claims 15-30 and 32 are canceled herein, as directed to subject matter of non-elected Group II, without prejudice to prosecution of this subject matter in a later-filed divisional application. Claims 10-11 are withdrawn as directed to non-elected species. The remaining claims read upon the elected species and Group. Claim 8 reads on the elected species Tβ4 (see October 25, 2007 Office Action, page 3, line 21).

Claims 1-7, 9 and 12-14 are rejected as not supported by adequate written disclosure. The reason given is that the claims encompass a "variant/fragment of SEQ ID NO 1" without requiring a particular conserved structure. Claim 1 recites "LKKTET SEQ ID NO: 1 or a conservative variant thereof" and does not recite the term fragment. The phrase "conservative variant" is defined in the present specification in paragraph 26 (page 9 of the clean version of the substitute specification). Conservative variants of SEQ ID NO: 1 are those in which an amino acid is replaced by another biologically similar residue. Biologically similar residues are discussed and listed in paragraph 26. Paragraph 5 also

specifically teaches that the C- and N-terminal variants of SEQ ID NOS: 2 and 3 also fall within the definition of conservative variants.

Applicant submits, therefore, that the genus of claimed variants is specific and given in detail in terms of structure. The specification provides particular and defined structure to the sequences that fall within this genus. The genus thus is provided in such a manner as to distinguish members from non-members and to particularly identify what is claimed. Because the variants encompassed by the claim are disclosed with particularity in terms of structure, Applicant submits they are described under the standards of 35 U.S.C. §112, first paragraph. Applicant therefore requests that this rejection be withdrawn.

Claims 1-7, 9, 12-14 and 31 are rejected as indefinite because the name of the well-known peptide Thymosin β4 may include post-translationally modified peptides having a different primary amino acid sequence. The Office indicates that skilled persons would not have been able to determine whether the claim encompassed all active and inactive variants and that examination cannot be performed without knowing the sequence.

Applicant has used the term Thymosin β4 as it is used in the art, and describes this polypeptide in paragraph 6 (page 2 of the clean copy of the substitute specification) as a 43 amino acid, 4.9

kDa polypeptide, thus eliminating the Office's purported concern about post-translational changes to the primary structure (processing which cuts the protein chain). Thymosin β4 is accepted in the art as a specific peptide hormone with a specific structure (sequence) and is not indefinite under the standards of 35 U.S.C. §112, second paragraph. The patent statute requires that claim terms apprise the skilled person of its scope, in light of the content of the disclosure, the prior art teachings and the claim interpretation that would be given by a skilled person.

In effect, therefore, the Office is asserting that the skilled person in the art would not understand what is thymosin β4 and what is not thymosin β4, even though the Office admits that thymosin β4 is a well-known term. The Office deems the specific term "thymosin β4" indefinite because peptides in general can undergo post-translational modification and <u>may</u> have different sequences. No evidence whatsoever, is provided which indicates this is the case for thymosin β4, however, or that, even if thymosin β4 is post-translationally modified, a skilled person would not be able to recognize what is or is not thymosin β4. Applicant would like to remind the Office that it bears the burden of showing a term is indefinite and may not reject a claim based on mere surmise about proteins in general or other molecules not claimed and then require the Applicant to disprove the unsupported contention.

"Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art." M.P.E.P. §2173.05(t). Such claims are not indefinite merely because a structure is not recited. Id. Applicant submits that the term "thymosin β4" is well-known and well-accepted in the art as referring to a specific polypeptide hormone. No skilled person would be confused by this term or fail to clearly understand its metes and bounds.

For the above reasons, Applicant submits that thymosin β4 is a clear and definite term with a specific and well-defined meaning to the person of skill, particularly in the complete absence of any evidence to the contrary. As such, any rejection of claims on this basis is improper. Applicants request withdrawal of this rejection.

The Office also has pointed out that it is unclear which component is an adhesive and which is a polypeptide in claim 1. Applicant has amended the claim to employ more traditional Markush language and to cancel redundant language in the preamble. No change in scope is intended by this amendment. Thus, it should be clear that the composition comprises (1) an adhesive and (2) a polypeptide belonging to the listed group. Applicant submits that the rejection is overcome. The word "fibrin," noted in the Office Action at page 5, line 19, is not recited in the rejected claim, and the Action does not explain why the length of SEQ ID NO: 1 is

relevant to the rejection. Applicant requests clarification if the Office intends to maintain this rejection.

Claim 31 has been amended in accordance with the Office's suggestion. Applicant submits the rejection is overcome.

Applicant requests withdrawal of the rejections made on grounds of indefiniteness at this time.

Claims 1-3, 9, 12-14 and 31 are rejected as anticipated by PCT published application WO 00/06190 (hereinafter "Kleinman"). The Kleinman reference is cited as teaching a composition that comprises LKKTET and a list of other components at page 10, lines 9-28. The reference, however merely teaches compositions that contain Tβ4 isoforms having the sequence LKKTET in them, and teaches that the compounds listed in the cited material also have the wound-healing activity and may be alternatives to the Tβ4 compound.

The fair teachings of Kleinman do not include compositions including an adhesive as recited in claim 1, however, and Kleinman is not even cited for teaching this feature of claim 1 here. Kleinman does not even mention adhesives. The Office therefore has not and cannot make out a prima facie case of anticipation against the present claims. Since this rejection is not proper, Applicant requests its withdrawal.

Claims 1-7, 9, 12-14 and 31 are rejected as obvious over Kleinman, discussed above, and U.S. Patent Publication No. 2003/0055511, herenafter "Schryver." The Kleinman reference is cited for teaching the compositions of the invention. However, Kleinman not only lacks and teachings of fibrin, as the Office concedes, but it also lacks teaching of compositions comprising any adhesive and a polypeptide, a feature recited in claim 1 here.

Schryver is cited as disclosing a composition that contains thymosin, Factor VIII and fibrin. This reference actually relates to a shaped particle for encouraging bone growth, which contains bone material, a bone morphogenic factor, and an angiogenic factor which may be thymosin β4. Fibrin is mentioned as an optional carrier for the suspended particles which has only two potential functions: encouraging bone growth and acting as a delivery vehicle. See Schryver, paragraph 174.

An adhesive function for fibrin is not mentioned or even hinted at in Schryver (or in Kleinman), nor is any benefit attributed to adding an adhesive to the Schryver or Kleinman compositions. Applicant therefore submits that it would not have been obvious to combine the products of Kleinman (which does not mention an adhesive or fibrin) and Schryver (which also does not mention an adhesive, any advantage an adhesive might have or that

fibrin could serve as an adhesive) to achieve the claimed invention here.

Nothing in any of the art guides a skilled person to use an adhesive with the composition claimed here (or even that fibrin is an adhesive), much less that the adhesive and the polypeptide components are covalently bound. Applicant submits that the present claims are not obvious over the cited disclosures since, even in combination, they fail to disclose all elements of the claims and there is no suggestion or hint in the references that would guide the skilled artisan to add the lacking features. Applicant therefore requests that the Office withdraw this rejection.

Applicant requests reconsideration of the application and prompt allowance of the claims as amended.

Respectfully submitted,

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